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July 7, 1999

Susan M. Pilch, Ph.D.
Nutrition Health Claims and Dietary Supplements
CFSAN, Office of Special Nutritionals
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Re: Health Claim Petition for Vitamin E Dietary Supplements and Heart Disease

Dear Dr. Pilch,

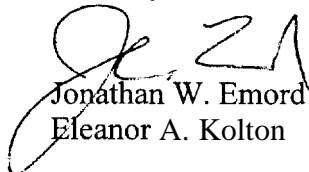
On behalf of Julian M. Whitaker, MD, American Preventive Medical Association, Durk Pearson and Sandy Shaw, and Pure Encapsulations, Inc. (collectively "Petitioners") we hereby submit this letter for association with the above referenced health claim petition filed on July 6, 1999. We supplement our original submission with the following information.

Analytical Methods:

In addition to the methods described in the US Pharmacopoeia (Attachment 3), the amount of vitamin E contained in a dietary supplement can be determined by Association of Official Analytical Chemists International (AOAC) official method numbers 939.09 and 988.14. Those official AOAC methods are described in the *Official Methods of Analysis of AOAC International*, 16th Ed. (Gaithersburg, MD: AOAC International), 1997, Chapter 45.

We are submitting an original and one copy of this letter. Feel free to call if you have any questions.

Sincerely,


Jonathan W. Emord
Eleanor A. Kolton

99P-4375

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